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Date: April 18, 2003
To: Examiner Anuradha Ramana
U.S. Patent and Trademark Office
Fax No: 703-308-2708
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Client No: 8627/096 (PA-5245-RFB)
Serial No: 09/815,567
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Carolyn Beason-Wright
Carolyn Beason-Wright

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41-23-B
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Ben

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PATENT**CASE NO.: 8627/096 (PA-5245-RFB)****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:)

Fred T. Parker)

Serial No.: 09/815,567)

Filed: March 23, 2001)

For: INTRODUCER SHEATH)

Examiner: Ramana, Anuradha

Group Art Unit: 3732

RESPONSE AFTER FINAL ACTION**BOX AF**

Commissioner for Patents and Trademarks
U.S. Patent and Trademark Office
Washington, DC 20231

Dear Sir:

This paper is responsive to the Office Action mailed February 20, 2003, wherein the Examiner issued a final rejection of all claims 1-21. Reconsideration is respectfully requested in view of the following remarks.

Claims 1-2, 4-5, 10-13 and 15-20 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al. (US 5,792,124) in view of Park et al. (US 6,159,187). Claim 3 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Parker (US 5,380,384). Claims 6-9 and 21 were rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of Ju et al (US

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5,599,325). Claim 14 was rejected under 35 U.S.C. §103(a) as being unpatentable over Horrigan et al in view of Park et al as applied to claim 1, and further in view of MacDonald et al (US 6,210,396).

As stated by the Examiner in the Office Action, the primary Horrigan reference discloses a catheter having some features in common with the claimed invention, but does not teach the use of a flat wire coil as a reinforcement means. The Park reference was cited for its teaching of a catheter section having a "braided wire coil."

The present invention is directed to an improved introducer sheath having a thin-walled construction and resistant to kinking. When an introducer sheath kinks during a medical procedure the sheath becomes unusable and cannot be straightened. As a result, the sheath must be removed, thereby leaving an enlarged, bleeding opening which typically cannot be reused for percutaneous entry. Increasing the thickness of the sheath wall in an attempt to avoid kinking is undesirable because the increased wall thickness reduces the ability of the sheath to pass through narrow bodily passageways. In addition, increased wall thickness necessitates enlargement of the entry hole, which is also undesirable.

In the final Office Action the Examiner disregarded Applicant's arguments that the use of a wire coil in the present application is preferable to Horrigan's use of a braided wire. Furthermore, the Examiner pointed out that the claims are silent as to the dimensions (wall thickness and outer diameter) of the introducer. In response, Applicant respectfully submits that those skilled in the art are well aware of the desirability of making the walls of an introducer sheath as thin as possible. Nonetheless, in spite of such awareness, Horrigan still chose to utilize a wire braid as a reinforcement means rather than a wire coil as in the present invention.

Since the strands of a wire overlap each other in woven fashion in a wire braid, it is apparent that a wire braid has a greater diameter than a wire coil (all other things equal). As a result, the use of a braid results in an introducer wall having a greater wall thickness than when a coil is used as the reinforcer. When even small reductions in introducer diameter can reduce trauma to the patient, the use of an introducer having a coil reinforcement is advantageous when compared to the use of the braid in Horrigan. Express dimensions are not necessary to illustrate this clear distinction, because the dimensions themselves are not the distinguishing factor. Rather, it is the fact that a braid inherently is made up of overlapping

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filaments (resulting in a greater diameter), whereas a wound coil does not have overlapping filaments (and therefore a lesser diameter).

In addition to the foregoing, there is yet another significant distinction between the use of a coil compared to the use of a wire braid. It is known in the art that the use of a wire braid reinforcement provides favorable torsional control when compared to a wire coil (torsional control being a stated objective of Horrigan), but that a wire coil has better kink resistance than a wire braid. Flexibility at the distal end of the sheath is a key feature of the present invention. For the tubing to be able to flex without kinking, the material on the outer part of the bend must stretch, and the material on the inner part of the bend must compress. The very nature of a braid (overlapping woven fibers or filaments) is such that it resists expansion and compression. The mere combination of lower durometer materials with a braided reinforcement defeats the purpose of the lower durometer materials, and results in a tube that is only marginally more flexible. The combination of lower durometer materials with a coil reinforcement, on the other hand, allows the distance between the turns on the inside of the bend to be increased very easily upon bending with absolute minimum force. This combination results in a tube structure that is much more flexible and kink resistant than an otherwise comparable structure having a braided reinforcement.

Neither Horrigan nor the secondary references recognize the importance of the coil to flexibility. In fact, the Horrigan construction results in a tip portion that is dominated by the properties of the braid. The drawings in the present application illustrate how the inner and outer layers of the coil have the ability to stretch and compress as necessary. This allows the sheath to have true flexibility that is a function of the inner and outer tube layers and not the reinforcement.

As stated in Applicant's previous response, the use of a reinforcement composition such as that taught in the Park reference adds complexity and manufacturing cost to a catheter. The function of the nitinol reinforcement taught in Park is to enable the structure to form a self-selected shape upon application of a modest amount of heat, and to retain that shape upon cooling. Although Park mentions that kink-resistance is a desirable feature of such catheters, it seeks to address the kink-resistance problem in a much more elaborate and costly manner when compared to the straightforward manner in which the problem is addressed in the present invention. Furthermore, it is noteworthy that the only drawings in Park that illustrate the use of a coil (Figs. 7 and 8), as contrasted to the use of a braid, do not

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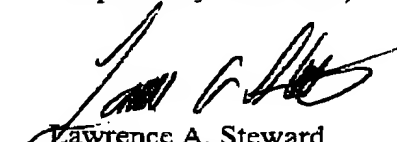
show the coil used in combination with inner and outer tubes. Rather, the reinforcing coil (232, 236) itself provides the lumen from one end of the structure to the other. No inner tube is present.

Applicant respectfully submits that absent the use of hindsight gleaned from the teachings of the present invention, one skilled in the art would not combine such disparate teachings to arrive at the claimed invention. This is particularly so in view of the clear preference that the references teach to the presence of a wire braid intermediate the inner and outer sheath tubes, rather than the use of a coil as claimed in the present application. Therefore, for all of the foregoing reasons, Applicant respectfully submits that claim 1 is not obvious in view of the cited combination.

According to the Office Action, Parker was cited for its teaching of an inner tube having a roughed outer surface. Ju was cited for its teaching of an outer sheath tube made from a blend of a polymer and a radiopaque filler. MacDonald was cited for its teaching of an outer tube comprising first and second tube sections of different colors. Applicant respectfully submits that nothing in these teachings overcomes the shortcomings recited above with regard to the rejection of claim 1.

Based upon the foregoing, Applicant respectfully submits that all claims 1-21 are in condition for allowance, and reconsideration of the rejections is respectfully requested. If the Examiner believes that the prosecution of this application may be expedited by a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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